

**510(k) Summary**General Information

DEC 02 2002

Classification	Class II
Trade Name	Solera™ Magnum Thrombectomy Catheter
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054  408-980-8300
Contact	Gregory J. Mathison Vice President, Clinical and Regulatory Affairs, Quality Assurance

Intended Use

The Solera Magnum Thrombectomy Catheter permits mechanical thrombectomy of synthetic dialysis grafts.

Predicate Devices

**Solera Thrombectomy Catheter** K003570  
Manufactured by Bacchus Vascular, Inc.

Device Description

The Solera Magnum is a single-use, over-the-wire disposable catheter, with an integral Motor Drive Unit (MDU). The Solera Magnum has a central hollow drive shaft connected to an expanding clot maceration and removal system. The clot removal system is comprised of a Nitinol macerator and a Nitinol outer protective basket. The macerator is attached to the drive shaft and rotates within the stationary protective basket. The protective basket expands to the lumen diameter and acts to protect the graft wall from the rotating macerator. Mechanical aspiration is achieved by rotation of the drive shaft and by an applied vacuum (locking syringe). The rotation of this drive shaft in conjunction with the vacuum causes material to be pumped out of the treatment area after maceration. Aspiration is controlled (i.e., on/off) by a button on the motor drive unit, which may be activated by the physician to allow flow out of the Solera Magnum. The default position is 'off' to and is designed to minimize blood loss during the procedure.

Materials

All materials used in the manufacture of the Solera Magnum are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Solera Magnum Thrombectomy Catheter was tested in the same manner as the Solera Thrombectomy Catheter (K003570). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Solera Magnum was designed under the Bacchus Quality System which is in compliance with 21CFR§820.30. ✓

Summary of Substantial Equivalence

The Solera Magnum Thrombectomy Catheter is equivalent to the predicate product, the Solera Thrombectomy Catheter. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Solera Magnum Thrombectomy Catheter is substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 02 2002

Bacchus Vascular  
c/o Mr. Gregory J. Mathison  
3110 Coronado Drive  
Santa Clara, CA 95054

Re: K022640  
Solera™ Magnum Thrombectomy Catheter  
Regulation Number: 870.4875  
Regulation Name: Peripheral Atherectomy Catheter  
Regulatory Class: Class II (two)  
Product Code: MCW  
Dated: November 21, 2002  
Received: November 22, 2002

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

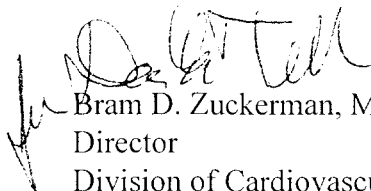
Page 2 – Mr. Gregory J. Mathison

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known):

This application

Device Name:

Solera™ Magnum Thrombectomy Catheter

Indications for Use:

The Solera Magnum Thrombectomy Catheter permits mechanical thrombectomy of synthetic dialysis grafts.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

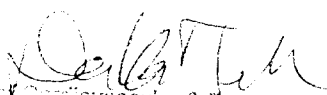
Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
Director, Center for Devices and Radiological Controls  
510(k) Number K023045